

REMARKS

Reconsideration of the claims in view of the following remarks is respectfully requested.

1. Status of the Claims

Claims 1, 4, 5, 8-21, 24 and 27-32 stand pending. Claims 2-3, 6-7, 22-23, and 25-26 stand canceled. Claims 1, 4, 5, 15-18, 21, 24, 27 and 29-35 stand rejected. Claims 8-14, 19-20, and 28 are withdrawn.

2. Title of the Invention

Applicants submitted an amendment to the title in the Preliminary Amendment filed October 20, 2004. Applicants further submitted a request for corrected Official Filing Receipt on September 13, 2007 to correct the title. The Office has not provided a copy of the corrected Official Filing Receipt, and the title has not been updated in PAIR. Applicants respectfully request the title be changed in the PALM/PAIR system, and a corrected Official Filing Receipt be mailed.

3. Rejection of the Claims Under 35 U.S.C. § 103(a)

A. Obviousness of claims 1, 4, 5, 33, and 35 over *Williams* in view of *Egger*

Claims 1, 4, 5, 33, and 35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Williams et al.*, "Lipids of *Ankistrodesmus braunii*," 133 *Science* 459 (1961) (hereinafter "*Williams*") in view of *Egger et al.*, "The Ketocarotenoids in *Adonis Annua L.*—II on the structure of esters," 6(3) *Phytochemistry* 437 (1967) (hereinafter "*Egger*"). The Office alleges that *Williams* discloses that lipids of *Ankistrodesmus braunii* contain astaxanthin and fatty acid fractions that includes capric acid and caprylic acid. The Office further alleges that *Egger* discloses that fatty acid compounds of ketocarotenoid esters in the petals of *Adonis annua* contain capric acid. The Office concludes that it would have been obvious to produce a purified form of an astaxanthin medium chain-fatty acid ester within the scope of claim 1 from the teachings of *Williams* and *Egger*.

Applicants traverse the rejection. Neither *William* nor *Egger* disclose a purified astaxanthin medium-chain fatty acid ester, wherein the medium-chain fatty acid ester is a monoester and the medium-chain fatty acid has 8 to 10 carbon atoms as recited in the claims.

Williams discloses a method of isolating methyl esters of fatty acids in which capric acid and caprylic acid are found in trace amounts. *See, e.g.*, p. 459. *Williams* further discloses isolating free astaxanthin. *See, e.g.*, p. 459. *Williams* fails to disclose an isolated or purified ester of astaxanthin and fatty acid, much less the claimed purified astaxanthin medium-chain fatty acid monoester.

Egger discloses esters from astaxanthin, and allegedly the ester includes fatty acids where capric acid is in a minor concentration. *See, e.g.*, abstract. *Egger* fails to disclose at least a purified astaxanthin medium-chain fatty acid monoester, wherein the fatty acid has 8 to 10 carbons. For example, the main fatty acid in the astaxanthin fatty acid ester of *Egger* includes myristic acid and other fatty acids having more than 10 carbons. Therefore, even if the references were combined as alleged by the Office, the combination would still not include all of the elements of the claimed invention as required in a 35 U.S.C. § 103 rejection.

Because neither *Williams* nor *Egger* disclose at least a method of isolating an astaxanthin fatty acid ester, Applicants submit that there is no evidence in the cited references that would have suggested to one of ordinary skill in the art that the detected astaxanthin and fatty acid are derived from astaxanthin fatty acid ester. Therefore, even if the references were to be combined, such a combination would not have included all of the elements recited in the claims. Further, there is nothing in *Williams* or *Egger* that would have suggested an expectation of success in isolating an astaxanthin medium-chain fatty acid ester.

Additionally, the combination of *Williams* and *Egger* fails to teach all of the recited elements of claims 1, 33, and 35 for at least the following reasons:

- 1) Neither reference discloses an astaxanthin medium-chain fatty acid monoester;
- 2) The recited purified astaxanthin medium-chain fatty acid ester is not merely an obvious purification of an old product as alleged by the Office; and
- 3) The cited references teach away from a purified astaxanthin medium-chain fatty acid ester.

1. No disclosure of an astaxanthin medium-chain fatty acid monoester

Williams and *Egger* fail to disclose at least that either the algal oil or petals of *Adonis annua* L. contain an astaxanthin medium-chain fatty acid monoester as recited in claims 1, 33, and 35. Astaxanthin medium-chain fatty acid esters can be monoesters or diesters. However, the Office and the cited references are silent on whether the ester is a monoester.

Therefore, for at least this reason, *Williams* and *Egger* fail to disclose each and every element of the claims as required in a 35 U.S.C. § 103 rejection, and thus the rejection should be withdrawn.

2. The purified ester recited in the claims is not an obvious purification of an old product.

The Office alleges that the claimed invention is merely a purified form of an old product. The Office relies on *In re Cofer*, 354 F.2d 664, 148 U.S.P.Q. 268 (C.C.P.A. 1966) for this proposition.

First, *Cofer* is misinterpreted by the Office. The court makes clear that the Office must present adequate factual evidence to support a conclusion of obviousness, and whether the compound has the same usefulness alone is not sufficient. *Id.* at 271. The Office must explain why it should be found from the references or from the common knowledge that a person skilled in the art would regard the claimed product to be obvious. *Id.* The Office failed to provide such an explanation. Instead, the Office has merely stated that the purified product and old product have similar utility, and that one of ordinary skill in the art could have made the purified product. The mere statement that the claimed invention is “within” the capabilities of one of ordinary skill in the art is insufficient by itself to establish *prima facie* obviousness. See MPEP § 2143.01 (IV).

Nothing in *Williams* or *Egger* would have led one of ordinary skill in the art to isolate an astaxanthin medium-chain fatty acid ester as recited in the claims. *Williams* fails to disclose at least any utility or desire to isolate any astaxanthin fatty acid ester. *Williams* discloses use of the entire algal oil as a food item, with no mention of specifically using purified astaxanthin fatty acid ester in food. *Egger* discloses isolating ketocarotenoid esters containing astaxanthin and fatty acids, a minor component of which may be capric acid. *Egger* fails to disclose at least isolating astaxanthin medium-chain fatty acid ester as recited in the claims. For at least this reason, there would have been no reason or expectation of success to isolate an astaxanthin medium-chain fatty acid ester, and thus the rejection should be withdrawn.

3. The cited references teach away from a purified astaxanthin medium-chain fatty acid ester.

Williams and *Egger* teach creating and/or using long-chain fatty acid based esters; they do not teach not medium-chain fatty acid based esters. *Williams* discloses that the algal

oil contains only traces of caprylic acid and capric acid, and that the three principal fatty acids linolenic acid, oleic acid and palmitic acid make up approximately 100% of the total fatty acid concentration. *See, e.g.*, 3rd column of p. 459. In the same manner, *Egger* discloses that myristic acid is the main compound and capric acid makes up only a minor component. *See, e.g.*, abstract. Therefore, if *Williams*, *Eggers*, and/or common knowledge at the time of Applicants' invention provide any suggestion for isolating an astaxanthin fatty acid ester, at best it would have been for a long-chain fatty acid.

Further, *Williams* and *Egger* teach away from the proposed modification, at least because it would render the prior art unsatisfactory for its intended purpose. Thus, the proposed modification is not obvious. *See* MPEP § 2143.01 (V). *Egger* is silent, for example, as to any utility for the esters. *Williams* specifically states that the algal oil would be digestible and nutritious, because it has a similar fatty acid fraction to vegetable oil. Therefore, from the teachings of *Williams*, one of ordinary skill in the art would have understood that unless the fatty acid fraction of a compound is similar to the fatty acid fraction of vegetable oil, the compound would not be known as being digestible and nutritious. A purified form of astaxanthin medium-chain fatty acid ester would have a very different fatty acid fraction from vegetable oil, so *Williams* teaches away from the modification proposed by the Office. Thus, it would have been unobvious at the time of Applicants' invention to isolate a purified astaxanthin medium-chain fatty acid ester as recited in the claim, and the rejection should be withdrawn.

Claims 4 and 5 depend from claim 1; they are also not obvious for at least these same reasons. For at least these reasons, Applicants respectfully request withdrawal of the rejection, and allowance of the claims.

B. Obviousness of claims 21, 15-18, 24, and 34 over *Egger* in view of *Asami* and *Williams*

Claims 21, 15-18, 24, and 34 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Eggers* in view of U.S. Patent No. 6,265,450 to Asami et al. (hereinafter "*Asami*") and *Williams*. The Office alleges that *Eggers* discloses a fatty acid ester containing astaxanthin and capric acid. The Office further alleges that *Asami* discloses using astaxanthin esters in compositions for food and cosmetics. The Office also alleges that *Asami* discloses that any monoester of a saturated fatty acid is operable in an anti-stress composition, and that one of ordinary skill in the art could infer from *Asami* and *Williams* that astaxanthin medium-

chain fatty acid esters have nutritious value. Finally, the Office concluded that using an astaxanthin medium-chain fatty acid monoester as claimed in food or cosmetic compositions would have been a simple substitution of one known element for another yielding predictable results, and that the claimed percentage would be determined through routine experimentation.

Applicants traverse the rejection. The rejection is improper for at least the following reasons:

- 1) None of the cited references disclose an astaxanthin medium-chain fatty acid monoester;
- 2) *Asami* is misinterpreted; it teaches away from medium-chain fatty acids;
- 3) The references teach away from using medium-chain fatty acid esters; and
- 4) No reason to modify the cited references to have at least 0.1% of an astaxanthin medium-chain fatty acid monoester.

1. None of the cited references disclose an astaxanthin medium-chain fatty acid monoester.

First, as discussed above, *Eggers* at least fails to disclose an astaxanthin medium-chain fatty acid monoester. Neither *Asami* nor *Williams* cure this deficiency. *Williams* is silent at least as to whether the ester is a monoester or diester. *Asami* discloses monoesters and diesters, and suggests to one of ordinary skill in the art that diesters are preferred. *See, e.g.*, col. 6, ll. 28-40. Therefore, at most, the teachings of *Eggers* and *Asami* taken as a whole for what they teach would have suggested to one of ordinary skill in the art to select diesters, and not monoester. Thus, there is no predictable reason or expectation of success to modify the references to include a monoester, and the rejection should be withdrawn.

2. *Asami* is misinterpreted and leads away from medium-chain fatty acids.

Second, *Asami* does not, as alleged by the Office, disclose that any monoester of a saturated fatty acid is operable in an anti-stress composition. *Asami* only states that “in the present invention, esters of astaxanthin include monoesters or diesters of saturated fatty acids such as palmitic acid and stearic acid.” *See, e.g., Asami* col. 6, ll. 28-30. This statement reasonably provides that palmitic acid and stearic acid are contemplated for use in the composition of *Asami*. When reading “saturated fatty acid” in context with the specific fatty acids described, *Asami* is clearly using the term merely to differentiate from unsaturated fatty

acids. *Asami* is not using the term to incorporate each and every saturated fatty acid in the invention. Instead, one of ordinary skill in the art would have recognized that *Asami* when viewed as a whole only contemplates long-chain fatty acids (i.e. 16 carbons or greater) and the term “saturated fatty acids” is referring to saturated long-chain fatty acids.

The scope and content of *Asami* includes esters of astaxanthin formed by esterification with fatty acids and says that both saturated fatty acids and unsaturated fatty acids can be used. See, e.g., *Asami* col. 6, ll. 28-34. *Asami* teaches that it is preferred to use unsaturated fatty acids because they create an astaxanthin ester that is more stable. See, e.g., *Asami* col. 6, ll. 34-40. All of the expressly described species are long-chain fatty acids containing at least 16 carbon atoms. See, e.g., *Asami* col. 6, ll. 28-34. Although *Asami* recites saturated fatty acids and unsaturated fatty acids generically, based on the expressly described species for both, it is clear *Asami* did not contemplate the use of medium-chain fatty acids. Further, “unsaturated” and “saturated” are being used in *Asami* to differentiate two lists of long-chain fatty acids, not to describe generically every known fatty acid. Therefore, the disclosure of *Asami* suggests a preference for astaxanthin esters containing long-chain unsaturated fatty acids and that any contemplated saturated fatty acids are long-chain fatty acids.

The differences between the scope of *Asami* and the scope of the claimed invention are substantial. The closest described fatty acids are palmitic acid with 16 carbon atoms in *Asami* compared to a fatty acid containing 10 carbon atoms in the claimed invention. Applicants have discovered that astaxanthin medium-chain fatty acid esters, which include fatty acids with substantially less than 16 carbon atoms, improve intestinal absorption rates. See, e.g., Specification p. 5, l. 17 – p. 6, l. 12. For example, Applicants’ Figures 1 and 2 show the superior digestibility of C8 fatty acid monoesters compared to C8 fatty acid diesters and Astax9000H manufactured by Itano, which is an extracted naturally occurring mixture of astaxanthin esters. See, e.g., Specification p. 4, l. 24 – p. 5, l. 10 and Figs. 1 and 2. Therefore, there is no reason or expectation of success in using an astaxanthin medium-chain fatty acid monoester in a food or cosmetic, and thus the rejection should be withdrawn.

3. The references teach away from using medium-chain fatty acid esters.

As shown above, *Williams* and *Eggers* teach away from using medium-chain fatty acid esters as digestible and nutritious. Further, *Asami* fails to cure this deficiency, at least because *Asami* only describes long-chain fatty acid esters, and reinforces the teachings of

Williams and *Eggers* that long-chain fatty acid esters are digestible and nutritious with silence on those properties of medium-chain fatty acid esters. The Office has incorrectly stated that one of ordinary skill in the art would have inferred from the teachings of *Williams* and *Asami* that astaxanthin medium-chain fatty acid esters have nutritious value. This inference is incorrect for at least the above reasons. Therefore, one of ordinary skill in the art would have failed to produce a composition containing an astaxanthin medium-chain fatty acid monoester, because the cited references teach away from such a modification.

4. No reason to modify the cited references to have at least 0.1% of an astaxanthin medium-chain fatty acid monoester.

Finally, even if it were obvious to substitute the algal oil of *Williams*, or the esters of *Eggers*, for the esters described in *Asami*, there is no suggestion or evidence to support the conclusion that it would have been obvious for the composition to contain at least 0.1% of an astaxanthin medium-chain fatty acid monoester as claimed. First, as shown above, there is no disclosure in *Williams* or *Eggers* of a monoester. Second, although the Office alleges that the concentration would be determined through routine experimentation. The obviousness of discovering an optimum value of a variable in a known process is predicated on whether the parameter optimized was a recognized result effective variable. *In re Antonie*, 195 U.S.P.Q. 6, 8-9 (C.C.P.A. 1977) (explaining the limits of the general optimization rule laid out in *In re Aller*, 105 U.S.P.Q. 233 (C.C.P.A. 1955)). The cited references and common knowledge of one of ordinary skill in the art at the time of Applicants' invention was that astaxanthin long-chain fatty acid esters were known and preferred, and that medium-chain fatty acid esters were only found in trace amounts. Therefore, because one of ordinary skill in the art would not have recognized medium chain fatty acid esters as recited in the claims to be result effective variables, there would have been no reason to optimize the concentration of the medium chain fatty acid esters in the composition.

Further, the amount of astaxanthin medium-chain fatty acid ester would have been expected to be less than 0.1% in the composition. The medium-chain fatty acid concentration was only known to be in trace amounts, and *Asami* discloses that the total fatty acid ester concentration in a composition is between 0.001% and 10%. *See, e.g.*, col. 8, ll. 4-11. Therefore, the concentration of medium-chain fatty acid concentration in a composition suggested by the cited references would be 10% or less of a trace amount, which is certainly

less than 0.1%. Thus, for at least the above reasons, the rejection is improper and should be withdrawn.

Dependent claims 15-18 and 24, which depend from claim 21, are also not obvious for at least these same reasons. For at least these reasons, Applicants respectfully request withdrawal of the rejection, and allowance of the claims.

C. Obviousness of claims 27, 29, 31, and 32 over *Williams* in view of *Asami*

Claims 27, 29, 31, and 32 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Williams* in view of *Asami*. The Office alleges that *Williams* discloses that lipids of *Ankistrodesmus braunii* contain astaxanthin and fatty acid fractions that includes capric acid and caprylic acid. The Office further alleges that *Asami* discloses using astaxanthin esters in compositions for food and cosmetics. The Office also alleges that *Asami* discloses that any monoester of a saturated fatty acid is operable in an anti-stress composition, and that one of ordinary skill in the art could infer from *Asami* and *Williams* that astaxanthin medium-chain fatty acid esters have nutritious value. Finally, the Office concluded that using an astaxanthin medium-chain fatty acid monoester as claimed in food or cosmetic compositions would have been a simple substitution of one known element for another yielding predictable results, and that the claimed percentage would be determined through routine experimentation.

Applicants traverse the rejection. As explained above, *Williams* fails to suggest any astaxanthin fatty acid ester, much less a composition comprising at least 0.1% of one astaxanthin octanoic acid monoester as recited in claim 27. Further, *Asami* fails to remedy this deficiency, at least for the reasons provided above. There is no reason to form a composition with the recited concentration of the astaxanthin octanoic acid monoester, and *Asami* and *Williams* both fail to suggest the use of a monoester containing octanoic acid. Therefore, for at least the reasons provided above the rejection is improper and should be withdrawn.

Dependent claims 29, 31, and 32, which depend from claim 27, are also not obvious for at least these same reasons. For at least these reasons, Applicants respectfully request withdrawal of the rejection.

4. Claim 30 is not rejected

Applicants note that although the Office Action summary and status of claims section of the Office Action indicate that claim 30 is rejected, the Office has failed to reject claim 30 under any statute. Any claim not rejected should be indicated as allowable. Applicants respectfully request the next response from the Office properly indicate the allowability of claim 30.

CONCLUSION

Reconsideration and reexamination of the claims is respectfully requested. If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0573. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is respectfully requested and the fee should also be charged to our Deposit Account. If any issues remain outstanding, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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